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10/057,116	01/24/2002	Todd K. Whitehurst	05-00604-01	1864

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EXAMINER	
SCHAETZLE, KENNEDY	
ART UNIT	PAPER NUMBER
3766	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/057,116	WHITEHURST ET AL.	
	Examiner	Art Unit	
	Kennedy J. Schaetzle	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-6,8,15,27 and 29-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-6,8,15,27 and 29-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 15 is objected to because of the following informalities: reference to "the stimulation parameters" in the generating step lacks antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 4-6, 8, 27, 29, 30, 33, 34 and 43-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al. (WO 98/37926) in view of Novak et al. (the article entitled: "Outcome Following Implantation of a Peripheral Nerve Stimulator in

Patients with Chronic Nerve Pain"), Rogers et al. (the article entitled: "Surgical aspects of chronic post-thoractomy pain") and Tannenbaum (Pat. No. 4,233,986).

Regarding claim 4, Schulman et al. disclose providing at least one leadless stimulator (100) having at least two electrodes (112a and 112b); implanting the at least one stimulator adjacent to at least one nerve (see page 3, lines 9-14), at least in part responsible for sensations in a region experiencing pain (note page 6, lines 10-13); generating stimulation pulses in accordance with stimulation parameters (page 8, line 31- page 9, line 2); delivering the stimulation pulses to nerves adjacent to the at least one stimulator (see page 12, lines 5-9).

Although Schulman et al. do not explicitly discuss a method for treating *chronic* pain, Schulman et al. teach that the device may be used to treat pain in general (see page 6, lines 10-16). It is further taught that a rechargeable battery may be employed in those applications requiring longer treatment times due to the *recurring* nature (i.e. chronic; also note the comments pertaining to chronic pain and its recurrent nature under the "Introduction" heading of the Rogers et al. reference) of the ailment (note for example page 8, lines 8-23 and page 20, line 20- page 21, line 6).

Novak et al. teach that an identified patient with chronic pain can be successfully treated with a peripheral nerve stimulator (see the last paragraphs on pages 1969 and 1971). Given the fact that one of the intended uses of the Schulman et al. device is to treat pain via nerve stimulation, and given the teaching that the implant may be powered indefinitely from an external power source depending on the particular application at hand, with the treatment of chronic pain by peripheral nerve stimulators known, those of

ordinary skill in the art presented with a patient experiencing chronic pain, would have seen the obviousness of utilizing the method of Schulman et al. to block chronic pain and provide a measure of relief to the patient.

Regarding the limitation concerning peripheral nerves, because the device of Schulman et al. with its relatively small size is capable of being placed in virtually any region of the body that may require nerve stimulation treatment, and because Schulman does not limit his method to any one nerve in particular, it would have been obvious to implant the device near a peripheral nerve if the peripheral nerve required stimulation – especially in view of the teachings of Novak et al. who suggest that such stimulation would be successful (see the last paragraphs on pages 1969 and 1971). The type of pain to be treated and the physiology of the nervous system would naturally dictate where the most effective application site resides.

Regarding the limitation directed to placement of the electrodes adjacent to at least one peripheral nerve in the thorax of the patient, the Rogers et al., Tannenbaum and Novak et al. references are additionally relied upon as detailed below.

Rogers et al. address treatment of chronic post-thoracotomy pain (see Introduction) resultant from intercostal nerve damage (see for example section 2 “Epidemiology,” section 3.1 “Intercostal nerve damage” etc.). Various drug treatments are suggested, but if proven ineffective, then measures such as nerve blocks and transcutaneous electrical nerve stimulation (TENS) may be necessary (see Section 5). Attention is also invited to par. 0005 of the present invention.

Tannenbaum additionally discloses a TENS device (those of ordinary skill in the art would readily recognize that Tannenbaum's TES device relates to what is more commonly referred to as a TENS device –the difference only being a matter of semantics) for the treatment of chronic pain such as various forms of neuralgias including intercostal and sternal pain (see col. 4, lines 26-31; col. 5, lines 26-41) as well as chest pain after open heart surgery, thoracotomy, mastectomy, et cetera (col. 4, lines 16-26). The importance of treatment in patients suffering from systemic diseases in which drug treatment has been ineffective is emphasized. Further, like Rogers et al., Tannenbaum teaches that TENS may be combined with nerve blocks if so desired (col. 5, lines 48-56). As is old and well-known in the art, Tannenbaum additionally discloses that the TENS electrodes should be located in the region of pain (col. 2, lines 6-11).

Novak et al. state that while TENS treatment has been used successfully to treat pain, the external electrodes can be cumbersome and may cause skin irritation. It is also taught that surgical implantation of electrodes proximal to the nerve not only remedies the above disadvantages, but may be more successful in treating chronic pain in that it allows more direct stimulation of the nerve (p. 1969, col. 2, 2nd full paragraph).

Those of ordinary skill and creativity in the art when presented with a patient experiencing chronic chest pain such as chronic post-thoracotomy pain, intercostal and sternal neuralgia, etc., given the suggestions of Rogers et al. and Tannenbaum that peripheral nerve stimulation at the region of pain with a TENS device may be a viable treatment method, and the teachings of Novak et al. that one can improve on TENS stimulation by implanting the peripheral stimulator adjacent the targeted nerve, would

have seen the obviousness of implanting the nerve stimulator of Schulman et al. adjacent at least one peripheral nerve in the thorax to treat thoracic pain regions.

Regarding claims 5 and 6, see page 22, lines 7-17 of Schulman et al..

Regarding claim 8 (and independent claim 27), all of the above comments made in support of the rejection of similarly worded limitations in claim 4 apply here as well. As argued above, the treatment of intercostal pain with peripheral nerve stimulation was known in the art at the time of invention. As Tannenbaum discloses that the electrodes should be placed at the region of pain, those of ordinary skill in the art practicing common sense would have seen the placement of the Schulman et al. device in the intercostal region where the intercostal nerve resides of a patient experiencing intercostal pain to be obvious.

Regarding claims 30 and 46, the intercostal nerve inherently comprises a branch or division. In any event, those of ordinary skill in the pain treatment arts given the suggestion to place electrodes of a peripheral nerve stimulator adjacent the peripheral nerve in the region of pain, and given the suggestion that the intercostal nerve can be stimulated to successfully treat chronic pain, artisans presented patients experiencing pain in the region of an intercostal nerve branch or division would have seen the obviousness of attempting to stimulate this nerve region in order to treat the patients' pain.

5. Claims 15 and 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al. (WO 98/37926), Novak et al. (the article entitled: “Outcome Following Implantation of a Peripheral Nerve Stimulator in Patients with Chronic Nerve

Pain"), Rogers et al. (the article entitled: "Surgical aspects of chronic post-thoractomy pain"), Tannenbaum (Pat. No. 4,233,986) and Hill et al. (Pat. No. 7,010,345).

Regarding claim 15, comments paralleling those made in the rejection of claim 4 apply here as well. Regarding limitations directed to details of the sensor, note page 14, lines 9-28 of Schulman et al.. Hill et al. disclose a related device for treating thoracic pain wherein it is also taught that closed-loop feedback of sensor data such as the detection or prediction of ischemic related events may be used to affect control of stimulation (see for example the text abridging cols. 3 and 4). Such control enhances the effectiveness of pain treatment by detecting the presence of possible pain producing conditions and adjusting stimulation parameters to meet the demands of current and future situations rather than relying on set parameters that may not be optimally suited for the detected condition or individual under treatment. To utilize the sensor/feedback arrangement of Schulman et al. to determine stimulation pulses for stimulating peripheral nerves in the thorax based on sensed conditions would have therefore been considered obvious by those of ordinary skill in the art looking to optimize performance and treatment effectiveness.

Regarding claims 37-40, note the comments made above in the rejection of similarly worded claims.

6. Claims 31, 35 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al., Novak et al., Rogers et al. and Tannenbaum as applied to claims 4-6, 8, 27, 29, 30, 33, 34 and 43-46 above, and further in view of Magarian et al. (the article entitled: "Transcutaneous Electrical Nerve Stimulation (TENS) for Treatment of

Severe Angina Pectoris Refractory to Maximal Medical and Surgical Management --A Case Report").

Regarding claim 31 and similarly worded claims, Magarian et al. teach that TENS may be effective in the treatment of chronic cardiac pain (see for example p. 409, 3rd paragraph). Novak et al. state that while peripheral nerve stimulation such as TENS treatment has been used successfully to treat pain, the external electrodes can be cumbersome and may cause skin irritation. It is also taught that surgical implantation of electrodes proximal to the nerve not only remedies the above disadvantages, but may be more successful in treating chronic pain in that it allows more direct stimulation of the nerve (p. 1969, col. 2, 2nd full paragraph).

Those of ordinary skill and creativity in the art, when presented with a patient experiencing chronic cardiac pain, given the suggestion by Magarian et al. that peripheral nerve stimulation at the region of pain with a TENS device may be a viable treatment method, and the teachings of Novak et al. that one can improve on TENS stimulation by implanting the peripheral stimulator adjacent the targeted nerve, would have seen the obviousness of implanting the nerve stimulator of Schulman et al. adjacent at least one peripheral nerve in the thorax to treat the pain regions.

7. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al., Novak et al., Rogers et al., Tannenbaum and Hill et al. as applied to claims 15 and 37-40 above, and further in view of Magarian et al. (the article entitled: “Transcutaneous Electrical Nerve Stimulation (TENS) for Treatment of Severe Angina Pectoris Refractory to Maximal Medical and Surgical Management --A Case Report").

The rejection of claim 41 parallels the rejection of similarly worded claims 31, 35 and 47 above.

8. Claims 32, 36 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al., Novak et al., Rogers et al. and Tannenbaum as applied to claims 4-6, 8, 27, 29, 30, 33, 34 and 43-46 above, and further in view of Weiner (Pat. No. 6,505,075)

Regarding the treatment of chronic back pain, Weiner teaches that chronic pain may be effectively treated by peripheral nerve stimulation (see "Background of the Invention), with areas of the head, neck, trunk and limbs cited as suitable locations for electrode placement. Examples of neuralgias in the trunk that can be treated include low back pain or other spine pain (see the text abridging cols. 8 and 9, for example). Weiner also teaches (see text abridging cols. 9 and 10):

> The application of the present invention to other peripheral nerves with their corresponding maladies and neuromas will occur to those skilled in the art. Conversely, once neurological maladies or neuromas and their corresponding peripheral nerves have been identified, as will also occur to those skilled in the art, the present invention may be used to treat such maladies or neuromas. It is clear that those skilled in the art will be able to practice the invention described above as applied to any peripheral nerve or to treat any particular neuroma by applying the disclosed method to its corresponding peripheral nerve.

Given the suggestion that lower back pain and other pain along the spine may be successfully treated by a peripheral nerve stimulator, and given the suggestion that one of ordinary skill in the art would recognize the obviousness of applying treatment to any peripheral nerve once the neurological maladies or neuromas have been identified, any artisan presented with a patient experiencing chronic back pain in the thoracic region would have seen the obviousness of attempting to treat the pain by placing the

electrodes of the Schulman et al. system proximal to the peripheral nerve in the region of pain.

9. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al., Novak et al., Rogers et al., Tannenbaum and Hill et al. as applied to claims 15 and 37-40 above, and further in view of Weiner (Pat. No. 6,505,075)

The rejection of claim 42 parallels the rejection of similarly worded claims 32, 36 and 48 above.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy J. Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on M-F at 571 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kennedy J. Schaetzle/
Primary Examiner, Art Unit 3766

KJS
September 24, 2008